3/16/98

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DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

March 10, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

GEN. SPEC.
RELEASE
F# _____ DATE 3/10/98
Reviewed by:

Thomas L. Huff, Owner
Belknap Livestock Auction
RD #2
Dayton, Pennsylvania 16222

Dear Mr. Huff:

On February 11, 1998, your firm, Belknap Livestock Auction, located at RD #2 in Dayton, Pennsylvania was visited by Food and Drug Administration (FDA) Investigator Robert T. Vaughn in response to a United States Department of Agriculture (USDA) report regarding an illegal drug residue in a calf you offered for slaughter for human food from your livestock auction. The calf was purchased from your facility and was slaughtered at [redacted] Additional investigation by the FDA at [redacted] has revealed serious violation of Section 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about October 22, 1997 you offered a calf, back tag PABA4430, for sale for slaughter for human food from your livestock auction. The calf was purchased by livestock dealer [redacted] on October 22, 1997 who delivered the animal for slaughter for food at [redacted] on October 23, 1997. The calf was slaughtered at Rendulic Packing on October 23, 1997 and as a result of United States Department of Agriculture (USDA) testing was condemned. USDA testing revealed the presence of 44 ppm (parts per million) and 30 ppm sulfamethazine in the liver and muscle tissues of the animal respectively. This is considered to be an illegal tissue residue since the tolerance for sulfamethazine in edible bovine tissue is 0.10 ppm. The presence of sulfamethazine in the edible tissue from your animal at the concentration level detected renders the food from the animal to be adulterated under Section 402(a)(2)(D) of the Act, because it contains a new animal drug that is unsafe within the meaning of Section 512.

Our investigation found that you purchase and hold animals under

conditions that permit those bearing potentially harmful drug residues to enter the food supply. For example, you lack an adequate system for assuring that animals offered for sale for slaughter for food have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions are adulterated. Our inspection revealed that you possessed no record(s) which would enable you to trace the producer of the animal. Additionally, you possessed no record(s) or information regarding the medication status of the subject calf,and, therefore, you were unable to provide this information to the eventual buyer of the calf.

You should take prompt action to correct the above violations and establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

The violations listed above are not intended to be all-inclusive. It is your responsibility to assure that your operation is in compliance with the law. As a livestock dealer, purchaser, or hauler of animals, you are frequently the individual who introduces or offers for introduction into interstate commerce, adulterated animals ("food" under the Act). As such, you share responsibility for violating the Federal Food, Drug, and Cosmetic Act. To avoid future illegal residue violations you should take precautions such as:

1) implementing a system to determine from the source of these animals whether the animals have been medicated and with what drug(s); and,

2) if the animals have been medicated, implementing a system to withhold the animals from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissues. If you do not want to hold medicated animals, then they should not be offered for human food, and they should be clearly identified and sold as medicated animals.

Please note that it is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused adulterated (medicated) animals to be offered for slaughter for human food at a slaughterhouse that ships beef in interstate commerce, is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within fifteen (15) days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reasons for the delay and the timeframe in which correction will be achieved. Please include copies of any available documentation demonstrating that correction has been accomplished.

Your reply should be directed to the attention of James C. Illuminati, Compliance Officer, at the above address.

Sincerely yours,

Charles B. Thorne
Acting District Director
Philadelphia District

jci

cc: Dr. Max A. Van Buskirk, Director
PA State Bureau of Animal Industry
Agriculture Building
2301 North Cameron Street
Harrisburg, PA 17120

cc: John Sworen
USDA, FSIS, FO
701 Market Street
2B South
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Philadelphia, PA 19106-1516

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Manzoor H. Chaudry, DVM
Branch Chief, Residue Staff